

Remarks

The Invention:

The present invention relates to improved methods and reagents for detecting the expression of cell-surface molecules, e.g., HLA-DR and CD11b, on human peripheral blood cells. Previously, accurate measurements of cell-surface expression were hindered by the dynamic nature of expression, which resulted in measurements that changed over time in an uncontrolled and unpredictable manner. The present invention results from Applicant's unexpected discovery that the expression of cell-surface molecules can be stabilized by the addition of a lysosomotropic amine.

Status of the Claims

Claims 1-13, 25, 27, 39-45, 51, and 54 are pending.

Claims 1-13, 25, and 27 are withdrawn from consideration.

Claims 39-45, 51, and 54 are rejected.

Amendments to the Specification:

Applicant has amended the specification to update the status of applications cited at page 1 and page 22, as requested by Examiner, and to correct an obvious typographical error introduced in the Preliminary Amendment.

The amendments do not introduce new matter. Applicant requests entry of the amendments to the specification into the record.

Amendments to the Claims:

Applicant has amended independent claim 39 to describe the invention with greater particularity by further clarifying the time-dependent nature of the expression of the cell-surface molecule whose expression is to be stabilized. Support for the amendment is found in the description of the time-dependence of HLA-DR expression (e.g., page 7, paragraph two) and in the teaching that the invention is applicable to other such cell-surface molecules (paragraph spanning pages 31-32).

The amendments do not introduce new matter. Applicant requests entry of the amendments to the claims into the record.

The Rejection of Claims 39-45, 51, and 54 under 35 U.S.C. §112, first paragraph

Claims 39-45, 51, and 54 were rejected under 35 U.S.C. §112, first paragraph for reciting new matter, in particular, for reciting "for a cell surface molecule". Examiner stated that the specification describes stabilization only of cell-surface molecules whose expression is time-dependent:

While the office concurs that "cell surface molecule" is recited at page 32, line 2, it must be realized that this is to be taken in the context of what precedes in the same paragraph. Therein it is clear that applicant was not describing any and all "cell surface molecules" but, rather, those for which there is a "time dependence" (first two lines of para. spanning pages 31-32) of a signal obtained upon fluorescent antibody staining, and for which the signal can be stabilized over time (page 31, lines 1) by chloroquine (lysotropc [sic] amine).

Office action, page 2, last paragraph.

Applicant has amended claim 39 to specify that the cell-surface molecule is one that exhibits a time-dependent fluorescence signal during staining with a fluorescent antibody, i.e., the kind of time-dependent signal exhibited by the exemplified cell-surface molecules, HLA-DR and CD11b. The problem that the present invention solves is how to stabilize the time-dependent signal from such cell-surface molecules, and the solution provided by the invention is the inclusion of a lysosomotropic amine in the staining mixture, which element is recited in composition of claim 39. As Examiner has acknowledged, the specification describes that the invention exemplified by the stabilization of HLA-DR expression also applies to cell-surface molecules that exhibit such time-dependent signal (see the specification, paragraph spanning pages 31-32). Thus, the written description provided by the specification reasonably conveys to one of skill in the art that the application had possession, at the time of filing, of the invention of claim 39, as amended.

Applicant respectfully requests reconsideration and withdrawal of the rejection of claims 39-45, 51, and 54 under 35 U.S.C. §112, first paragraph, in view of the amendments and remarks.

The Rejection of Claims 39-45, 51, and 54 under the judicially created doctrine of obviousness-type double patenting

Claims 39-45, 51, and 54 under the judicially created doctrine of obviousness-type double patenting over claims 1-9 of U.S. Patent No. 6,200,766. Applicant submits herewith a terminal disclaimer in compliance with 37 C.F.R. 1.321(c).

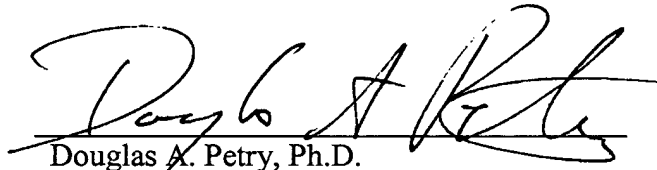
Applicant respectfully requests reconsideration and withdrawal of the rejection of claims 39-45, 51, and 54 under the judicially created doctrine of obviousness-type double patenting in view of the terminal disclaimer.

Conclusion

Applicant believes that all objections to the specification and rejections of the claims have been overcome and that the claims are now in condition for allowance. Applicant respectfully requests allowance of the pending claims.

Respectfully submitted,

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Date



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